K091902

510(k) Summary of Safety and Effectiveness
1.5T and 3.0T 8-Channel Small Extremity Coil

AUG 21 2009

Submitted By:	Invivo Corporation 3545 SW 47th Ave. Gainesville, FL 32608
Date:	June 23, 2009, revised August 6, 2009
Contact Person:	Elizabeth Wheeler, Regulatory Affairs Engineer Tel: (352) 336-0010, ext 164 Fax: (352) 336-1410
Proprietary Name:	1.5T and 3.0T 8-Channel Small Extremity Coil
Common Name:	Coil, Magnetic Resonance, Specialty
Classification Name and Reference:	21 CFR 892.1000, A magnetic resonance diagnostic device, for general diagnostic use to present images which reflect the spatial distribution and/or magnetic resonance spectra which reflect frequency and distribution of nuclei exhibiting nuclear magnetic resonance, class II.
Device Product Code and Panel Code:	MOS / Radiology / 90

Device Description:
The design of the 1.5T and 3.0T 8-Channel Small Extremity Coils are based on design features of the predicate device Musculoskeletal Flex Coil Package: Upper Extremity Flex Coil. The Small Extremity Coils are designed as receive only for high resolution diagnostic imaging of bone, soft tissue, musculoskeletal and vascular structures in small extremities. The Small Extremity Coils are manufactured of materials that are similar to those used to manufacture the predicate device and other Invivo Corporation coils.

Indications for Use:
The coil is indicated for use on the order of a physician, in conjunction with an MR scanner as an accessory to produce images of the upper and lower extremities, as an aid to diagnosis.

Technological Characteristics:
The fundamental scientific technology of a radio frequency (RF) coil is that the coil receives radio frequency signals from the tissue of interest.

The fundamental scientific technology of the subject device described in this submission has not been altered from the predicate device.

Substantial Equivalence Information:
When compared to the predicate device, Musculoskeletal Flex Coil Package: Upper Extremity Flex Coil and Lower Extremity Flex Coil –K983109, cleared 10/06/98, substantial equivalence is based on similarities in intended use, and technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

AUG 21 2009

Ms. Elizabeth Wheeler, MST, RAC
Regulatory Engineer
Invivo Corporation
3545 SW 47th Ave
GAINESVILLE FL 32608

Re: K091902
Trade/Device Name: 1.5T and 3.0T 8-Channel Small Extremity Coil
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: August 6, 2009
Received: August 7, 2009

Dear Ms. Wheeler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K091902

Device Name: 1.5T and 3.0T 8-Channel Small Extremity Coil

Indications for Use:

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K091902